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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/394,264	09/10/1999	CYNTHIA C. MORTON	10286/008001	3961

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EXAMINER
WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
1648	20

DATE MAILED: 02/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/394,264	MORTON ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *8-17 and 19-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,18 and 29-33* is/are rejected.

7)☒ Claim(s) *3 and 5-7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

A request for continued examination filed 1/18/2002 (Paper No. 18) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/18/2002 has been entered (Paper No. 19) Claim 34 has been cancelled. Claims 1-7, 18 and 29-33 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

The rejection of claims 1 and 30 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention **is maintained** for reasons of record. In the interview with applicant on 12/18/2001 it was indicated that the rejection made in the prior rounds have been based on the lack of a reliable measurable function that is to be associated with the claimed nucleic acid sequence. Applicants now have included both human and mouse sequences in the claims (specifically claim 1). In addition, the claims have been amended to add sequence identifiers for the von Willibrand factor and factor C using SEQ ID NO's. However, adding these variable sequences "at least 90%" as claimed does not help to further limit the claim, because the limitations of these factors are themselves vague and unascertainable due to the

variability. The claims now are drawn to a nucleic acid sequence which encodes an amino acid sequence, the nucleotide sequence thereby contains variability due to the degeneracy of the genetic code. Applicant's are attempting to obtain greater variability with the actual protein sequence, such variability may be permissible if protein as claimed provides a structure plus function. To meet the functional requirement, the function must be measurable by the ordinary artisan such as interaction a given binding activity binding or substrate turnover. As the claim are written applicant's attempt to identify the functionality as "having the ability to bind fibrillar collagen". This vague definition (see below) does not provide requisite function because the ordinary artisan is not sure that binding is even required and the specification is silent as to when the binding is to occur and when it does not. Therefore, the rejection is maintained for not being supported by a written description.

The rejections of claims 1 and 30 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention **is maintained** for reasons of record. In the interview with applicant on 12/18/2001 it was indicated that the rejection made in the prior rounds have been based on the lack of a reliable measurable function that is to be associated with the claimed nucleic acid sequence. Applicants now have included both human and mouse sequences in the claims (specifically claim 1). In addition, the claims have been amended to add sequences identifiers for the von Willibrand factor and factor C using SEQ ID NO's. However, adding these variable sequences "at least 90%" as claimed does not help to further limit the claim, because the limitations of these factors

are themselves vague and unascertainable due to the variability. The claims now are drawn to a nucleic acid sequence which encodes an amino acid sequence, the nucleotide sequence thereby contains variability due to the degeneracy of the genetic code. Applicants are attempting to obtain greater variability with the actual protein sequence, such variability may be permissible if protein as claimed provides a structure plus function. The functional aspect requires must be within the grasp of the ordinary artisan. As the claims are written, applicant's attempt to identify the functionality as "having the ability to bind fibrillar collagen". This vague definition (see below) does not provide requisite function because the ordinary artisan is not sure that binding is even required and the specification is silent as to when the binding is to occur and when it does not. Therefore, the rejection is maintained.

New rejections:

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "having the ability to bind fibrillar collagen" is indefinite because the ordinary artisan would not know under which circumstances the particular protein would need to /or would not need to bind fibrillar collagen.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claim refers to a "non-COCH5B2" polypeptide; the metes and bounds of this polypeptide are unclear. Technically, any polypeptide that has even a single amino acid

change would be considered "non-COCH5B2" polypeptide. Yet applicant in claim 1 is trying included variable sequences, therefore, it is not unclear at what point the molecule becomes a "non-COCH5B2" polypeptide.

Claims 1, 2, 18, 29, 30, 31, 32 and 33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

The claims are drawn to isolated nucleic acid molecule which according to the specification (see page 16) includes cDNA and genomic DNA. The specification discloses isolated cDNA sequence, SEQ ID Nos : 1 and 6, which encodes a predictive polypeptide sequence, SEQ ID NOs. 2 and 7. Absent evidence to the contrary, each of the SEQ ID NOS elected for examination is deemed to be cDNA. The claims, as written, however, encompass polynucleotides which vary substantially in length and in nucleotide composition, the genes also include undescribed 5' and 3' regulatory elements. The broadly claimed genus additionally encompasses genes as well as genes incorporating only portions of the disclosed sequence.

The instant disclosure of a single species of nucleic acid does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length genes. A description of a genus of cDNAs may be achieved by means of a recitation of a

representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of polynucleotides. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. There is no description, however, of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polynucleotides encompassed and no identifying characteristic or property of the instant polynucleotides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

The specification further fails to identify and describe the 5' and 3' regulatory regions and untranslated regions essential to the function of the claimed invention, which are required since the claimed invention currently encompasses the gene. The art indicates that the structures of genes with naturally occurring regulatory elements and untranslated regions is empirically determined (Harris et al. J. of The Am Society of Nephrology 6:1125-33, 1995; Ahn et al. Nature Genetics 3(4):283-91, 1993; and Cawthon et al. Genomics 9(3):446-60, 1991). Therefore, the structure of these elements is not conventional in the art and skilled in the art would therefore

not recognize from the disclosure that applicant was in possession of the genus of nucleic acid, including genes, comprising SEQ ID NO: 1 and 6 or fragments thereof.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of specific nucleotide sequences and the ability to screen, is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 18 is provisionally rejected under the judicially created doctrine of double patenting over claims 17-21 of copending Application No. 09/579288. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: The instant invention is claiming a kit comprising nucleic acid

sequences molecule that is able to hybridize with the nucleic acid molecule in claim 1, which is COCH5B2. Claims 17-21 of the copending Application No. 09/579288 is drawn to a kit comprising nucleic acid probes which bind COCH5B2.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 3 are 5-7 are objected to because of the following informalities: The claims are objected to because they are dependent on rejected claim 1. Applicant is advised that incorporating the limitations of claims 3 and 5-7 would not necessarily overcome the rejection of claim 1.

Conclusion

Claims 3 are 5-7 are objected to for depending on a rejected claim.

Claims 1, 2, 4, 18, 29 –33 are rejected.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Wood et al. PCT WO 99/14328 (applicant should examine figures 81 and 82).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.

JEFFREY STUCKER
PRIMARY EXAMINER